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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,822	REMACLE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) *1-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *15 October 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with Sequence Rules.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 45-86, with the subsequent election of the species nucleic acids, in response received 23 September 2003 is acknowledged.

2. Claims 1-44 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response received 23 September 2003.

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

4. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Specification

5. The use of the trademarks TWEEN, TRITON X-100, NONIDET P40 (NP40) have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

6. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Requirement for Information

7. An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: The claimed invention fairly encompasses microarrays on CDs. As an exemplification of such, the specification, through Example 8, pages 59-60, teaches of "Hepatochips" as being obtained from "AAT, Namur, Belgium" and that the array was read with a "Bio-CD reader." Applicant is required to provide information pertaining to the sale and use of "Hepatochips" and "Bio-CD reader" and how these products are encompassed, or not encompassed by the claims currently before the Office. Specific information relating to when each of these products was first offered for sale is required.

8. Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

9. Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

10. Applicant is required to provide information as to what material was newly added to the instant disclosure over that of both the parent application and priority document, Provisional Application 60/071,726.

11. In response to this requirement, please provide the names of any products or services that have incorporated the claimed subject matter.

12. In response to this requirement, please provide copies of each publication which any of the applicants authored or co-authored and which describe the disclosed subject matter of the elected claims.

13. This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventor(s), at the time the application was filed, had possession of the claimed invention.

Attention is directed to the decision of *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1111 (CAFC, 1991):

> This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the "applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

15. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co., et al.* (Fed. Cir. February 13, 2004):

> [A]n invention may be enabled even though it has not been described. See, e.g., In re DiLeone, 436 F.2d 1404, 1405 (CCPA 1971) ("[I]t is possible for a specification to enable the practice of an invention as broadly as it is claimed, and still not describe that invention."). Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B if B were described. A specification can likewise describe an invention without enabling the practice of the full breadth of its claims. Finally, still further disclosure might be necessary to satisfy the best mode requirement if otherwise only an inferior mode would be disclosed. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535 (Fed. Cir. 1987).
>
> The "written description" requirement serves a teaching function, as a "quid pro quo" in which the public is given "meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time." Enzo, 323 F.3d at 970.
>
> ***
>
> While it is true that this court and its predecessor have repeatedly held that claimed subject matter "need not be described in haec verba" in the specification to satisfy the written description requirement, e.g., In re Smith, 481 F.2d 910, 914 (CCPA 1973), it is also true that the requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." Enzo, 323 F.3d at 968. We have further explained that:
>
> > [T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening

> inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] . . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

Enzo, 323 F.3d at 968. Similarly, for example, in the nineteenth century, use of the word "automobile" would not have sufficed to describe a newly invented automobile; an inventor would need to describe what an automobile is, viz., a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect.

***

We of course do not mean to suggest that the written description requirement can be satisfied only by providing a description of an actual reduction to practice. Constructive reduction to practice is an established method of disclosure, but the application must nonetheless "describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations." Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998). But see Enzo, 323 F.3d at 969 ("Application of the written description requirement, however, is not subsumed by the 'possession' inquiry. A showing of 'possession' is ancillary to the statutory mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the invention."). The specification must teach the invention by describing it.

16. The claimed disc is to comprise a nucleotide sequence that is in turn to bind to a target molecule. As noted above, the specification must provide an adequate written description of what it is, and that such a description is not satisfied by assertions of how it is to function (it binds "target molecule(s)") or a general characterization of what it is ("nucleotide sequence").

17. While Example 8 teaches of using the "Rat HepatoChips ^{TM} (AAT, Namur, Belgium)," and page 61 describes the nucleic acids as being "single stranded DNA probes attached to the glass by a covalent link," and Table 2 defines the target molecule in terms of certain genes and how they are believed to function, such does not provide an adequate written description of the

immobilized nucleic acids, as such again speaks to functional attributes, and not physical or chemical properties that would allow a skilled artisan to recognize one sequence as being encompassed, or not encompassed, by the claims. Further, the record does not support the position that applicant possessed the nucleotide sequence for any and all target molecules, which fairly encompass any nucleic acid sequence that correlates with intelligence, aging, as well as correlating with any disease of any etiology, for any and all life forms.

18. As seen in claim 67, "the alignment of capture molecules is converted into digital information selected from the group consisting of words, numbers, music, software and data bases." A review of the disclosure fails to find an adequate written description of said "words, numbers, music, software and data bases."

19. Claims 73 and 86 are drawn to a kit. In accordance with Claim 73, the kit is to comprise *inter alia*, "reactants allowing the binding between the target molecule and its capture molecule and possibly reactants allowing the detection of a signal which results from said binding." As noted above, defining a product in terms of how it is to function and not in terms of what it is does not constitute an adequate written description of same.

20. In accordance with Claim 72, the disc is to v coated with a "protective layer." Example 13, page 66 of the disclosure, teaches of the application of a "varnish." The "protective layer" and "varnish" are assumed to be one and the same. The specification does not provide an adequate written description of just what the "varnish"/"protective layer" is comprised of. A review of the disclosure fails to locate an adequate description of either of these elements. Accordingly, the specification has not been found to provide an adequate written description of the claimed invention.

21. Claims 74-80 are directed to a "detection and/or reading device," which in accordance with claim 75 is "a compact-disc reading device." Page 66, lines 24-26, teaches that "[t]he reader device is based on a commercially available CD writer (Fig. 12-13)" (emphasis added). Page 8, lines 6-7, states:

> Figures 11 to 14 show various types of Bio-CD reading devices.

A review of the disclosure fails to locate and adequate written description of the claimed "detection and/or reading device," including the software that is required for its operation. While the claimed invention may be "based on commercially available CD writer," the specification must provide an adequate written description of the invention in terms of what it is.

22. Claims 80-85 are drawn to a "handling device" (claims 80-84) as well as an "apparatus" (claim 85). Like the disc and reader above, a review of the disclosure fails to find an adequate written description of either the handling device or the apparatus.

23. It is noted that the claimed invention is to be used in a method whereby a quantification event is to take place. Neither the disc, reader, handling device or apparatus are defined in terms of comprising any element or assembly of elements that will result in the quantitative determination of any nucleic acid.

24. For the above reasons and in the absence of convincing evidence to the contrary, claims 45-86 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.

Claims 45-86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

As set forth above, the specification does not provide an adequate written description of the claimed invention, including the nucleic acids that are to be immobilized to the surface of a disc. Said nucleic acids are an essential starting material to both the making and use of the claimed invention. Further, without the disc, the reader and handler cannot function. It is well settled that one cannot enable that which they do not yet possess, and that one cannot enable an

invention when the starting materials are not provided. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

For the above reasons, and in the absence of convincing evidence to the contrary, claims 45-86 are rejected under 35 USC 112, first paragraph, as not being enabled by the disclosure.

25. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

26. Claims 47, 48, 52 60, 63-64, and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

27. Claim 47 lacks antecedent support for "the registered data."

28. Claim 48 lacks antecedent support for "the registered data."

29. Claim 52 lacks antecedent support for "the location of the samples.

30. Claim 60 is indefinite with respect to the metes and bounds of "some."

31. Claims 63 and 64 lack antecedent support for "said portion."

32. Claim 71 is confusing as to what constitutes an "extremity of the capture molecule" when said capture molecule is a nucleic acid.

Double Patenting

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 45-69 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49 and 50 of copending Application No. 09/582,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a disc.

35. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 February 2004